Linking Hypotheses, Outcomes, and Assessment Measures

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I. Measurable Outcomes

- State hypotheses so that they specify measurable primary and secondary outcome constructs

Biobehavioral mood management treatment as compared to attention control will

- *increase smoking cessation (primary outcome)*
- *decrease depression (secondary outcome)*

among smokers with a prior history of major depression

II. Operational Definitions

- Operationalize each outcome by assessment measure(s)
  - ***Smoking cessation*** *(abstinence):*
    - *Self-report*
    - *Expired CO*
    - *Saliva cotinine*
  - ***Depression*** *(improvement)*
    - *Self-report (Beck, CES-D, PANAS)*
    - *Clinical rating (Hamilton Depression Scale)*
    - *Laboratory (Attentional bias toward negative cues)*
      - ***Which?!?***

III. Choosing Assessments

- Use reliable and valid measures
  - (currently disparate standards for biomeasures versus ratings, but be prepared for change)
- Keep subject burden as low as possible
- Accommodate accepted "gold standard," "best practices"
- Know and control sources of measurement error (e.g., cotinine for 48 hour abstinence)

III. Choosing Assessments

- ***Smoking cessation*** *(abstinence):*
  - *Self-report*
  - *Expired CO*
  - *Saliva cotinine*

  Use all?
- **Pros**: gold standard bioverification, multi-method triangulation on construct
- **Cons**: expense, burden, patient acceptance, increased missing data, unnecessary?
- **Options**: sample collection w/ random assay, bogus pipeline, random sample collection

III. Choosing Assessments

Depression

- *Self-report (Beck, CES-D, PANAS)*
- *Clinical rating (Hamilton Depression Scale)*
- *Laboratory (Attentional bias toward negative cues)*

Which?

– **Reliability AND sensitivity to change** (e.g., not trait neuroticism)

– Construct validity

- *Discriminant validity*: High negative affect (kvetching) is ubiquitous (anxiety, substance abuse, medical illness). Depression core = low positive affect, anhedonia (PANAS)
- *Is insight/recognition of depression required (e.g, nonpsychogically minded people)?* (attentional bias task)

IV. Measure who's excluded

- Categorize reasons for exclusion & tabulate cases
  - Uninterested
  - Couldn't reach
  - Insufficient severity (doesn't smoke enough)
  - Exclusionary comorbid condition
  - Alternative treatments
  - (for child) Parent declines permission

V. Measure when and why people go off protocol

- Got better, no longer interested
- Became ineligible
- Couldn’t quit, got discouraged
- No longer interested
- Moved (job change)
- Adverse event
- Couldn’t be reached

BUT DON’T STOP ASSESSING PRIMARY OUTCOME!!!

IX Measure treatment process variables/mediators

- Treatment Adherence/Enactment
  - Treatment attendance, homework, skill performance, took meds
- Theoretically active treatment processes (like a manipulation check)
  - Depression, weight concerns, self-efficacy, reward value

X. Measure likely moderators

- Therapist skill, warmth, communication ability, experience, training background
- Setting variables (church vs. hospital, waiting room pamphlets about smoking, designated behavioral interventionist in MD office)
- Temporal variables (season, year, major events – 9/11, earthquake)

XI: Time Assessments Strategically

- When things are expected to happen
- At what field considers the accepted benchmark intervals (EOT, 6 mos, 1 year)